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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1200]

Dietary Supplements Containing Ephedrine Alkaloids; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening from August 10 to September 30, 2000, the comment period for a notice that published in the **Federal Register** of April 3, 2000 (65 FR 17510), that announced the availability of new adverse event reports (AER's) and related information concerning dietary supplements containing ephedrine alkaloids. This action is being taken in conjunction with a separate **Federal Register** notice by the U.S. Department of Health and Human Services' Office of Women's Health (OWH), which is part of the U.S. Public Health Service (PHS), announcing that it will hold a public meeting on August 8 and 9, 2000, to discuss available information about the safety of dietary supplements containing ephedrine alkaloids. FDA is also giving notice of the availability of a report on phenylpropanolomine and risk of hemorrhagic stroke.

DATES: Submit written comments on the notice of availability by September 30, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: FDADockets@oc.fda.gov, or http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Comments are to be identified with the docket number found in brackets in the heading of this document.

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FOR FURTHER INFORMATION CONTACT: Marquita B. Steadman, Center for Food Safety and Applied Nutrition (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6733.

SUPPLEMENTARY INFORMATION:

I. Reopening the Comment Period

In the **Federal Register** of April 3, 2000 (65 FR 17510), FDA published a notice announcing a new public docket that makes available new AER's and related information concerning dietary supplements containing ephedrine alkaloids. The **Federal Register** notice (65 FR 17510) also announced FDA's intent to participate in a public forum to address safety information on such products. Interested persons were given until May 18, 2000, to submit written comments on the April 3, 2000, **Federal Register** notice to FDA's public docket (Docket No. 00N–1200). FDA later extended this comment period until July 3, 2000 (65 FR 32113, May 22, 2000).

In a separate **Federal Register** notice (65 FR 43021, July 12, 2000), OWH announced that it will convene a public meeting to discuss available information about the safety of dietary supplements containing ephedrine alkaloids. These products are promoted for uses such as weight loss, body building, and increased energy. This meeting will afford all interested persons an opportunity to provide focused comment in a manner that will assist PHS in understanding the benefits and risks associated with dietary supplements containing ephedrine alkaloids. The PHS public meeting is scheduled for August 8 and 9, 2000. For more information, refer to the July 12, 2000, **Federal Register** notice, or visit the OWH Internet site (The National Women's Health Information Center) at http://www.4woman.gov/owh/public.

In light of this public meeting, FDA is reopening the comment period for the April 3, 2000, notice from August 10 to September 30, 2000. The information and comments generated from the PHS public meeting, along with the information in the public docket (Docket No. 00N–1200), will be considered by FDA in assessing the safety of dietary supplements containing ephedrine alkaloids that are promoted for uses such as weight loss, body building, and increased energy.

The agency has added a report entitled ''Phenylpropanolomine and Risk of Stroke: Final Report of the Hemorrhagic Stroke Project'' to the public docket (Docket No. 00N–1200). The agency seeks written comment on this report and its relevancy to an assessment of the safety of dietary supplements containing ephedrine alkaloids.

II. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments from August 10 to September 30, 2000. You may also send comments to the Dockets Management Branch via the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm, or e-mail: FDADockets@oc.fda.gov. Comments are to be identified with the docket number found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

You may request a transcript of the PHS meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. You

may also examine the transcript of the meeting after August 25, 2000, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, as well as on the Internet at http://www.fda.gov.

Dated: 7/25/00
July 25, 2000

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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